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# ENVIRONMENTAL PROTECTION AGENCY

**40 CFR Parts 9 and 721** 

[EPA-HQ-OPPT-2015-0220; FRL-9927-67]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

SUMMARY: EPA is promulgating significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 22 chemical substances which were the subject of premanufacture notices (PMNs). Two of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action requires persons who intend to manufacture (including import) or process any of these 22 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

**DATES:** This rule is effective on [insert date 60 days after date of publication in the **Federal Register**]. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on [insert date 14 days after date of publication in the **Federal Register**].

Written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs must be received on or before [insert date 30 days after date of publication in the Federal Register] (see Unit VI. of the SUPPLEMENTARY INFORMATION). If EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs before [insert date 30 days after date of publication in the Federal Register], EPA will withdraw the relevant sections of this direct final rule before its effective date.

For additional information on related reporting requirement dates, see Units I.A., VI., and VII. of the **SUPPLEMENTARY INFORMATION**.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2015-0220, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- Mail: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <a href="http://www.epa.gov/dockets/contacts.html">http://www.epa.gov/dockets/contacts.html</a>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <a href="http://www.epa.gov/dockets">http://www.epa.gov/dockets</a>.

**FOR FURTHER INFORMATION CONTACT:** For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: moss.kenneth@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

### SUPPLEMENTARY INFORMATION:

### I. General Information

## A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

Manufacturers or processors of one or more subject chemical substances
 (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at

19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of a proposed or final rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

- B. What Should I Consider as I Prepare My Comments for EPA?
- 1. Submitting CBI. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.
- 2. *Tips for preparing your comments*. When preparing and submitting your comments, see the commenting tips at <a href="http://www.epa.gov/dockets/comments.html">http://www.epa.gov/dockets/comments.html</a>.

### II. Background

A. What Action is the Agency Taking?

EPA is promulgating these SNURs using direct final procedures. These SNURs will require persons to notify EPA at least 90 days before commencing the manufacture or processing of a chemical substance for any activity designated by these SNURs as a significant new use. Receipt of such notices allows EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. Additional rationale and background to these rules are more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** issue of April 24, 1990 (55 FR 17376)(FRL-3658-5). Consult that preamble for further information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

# B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use. Persons who must report are described in § 721.5.

# C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the

effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

# **III. Significant New Use Determination**

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the 22 chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

## IV. Substances Subject to this Rule

EPA is establishing significant new use and recordkeeping requirements for 22 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (assigned for nonconfidential chemical identities).
- Basis for the TSCA section 5(e) consent order or, the basis for the TSCA non-section 5(e) SNURs (i.e., SNURs without TSCA section 5(e) consent orders).
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VIII. for more information).
  - CFR citation assigned in the regulatory text section of this rule.

The regulatory text section of this rule specifies the activities designated as significant new uses. Certain new uses, including production volume limits (i.e., limits on manufacture volume) and other uses designated in this rule, may be claimed as CBI. Unit IX. discusses a procedure companies may use to ascertain whether a proposed use constitutes a significant new use.

This rule includes 2 PMN substances (P-13-930 and P-14-763) that are subject to "risk-based" consent orders under TSCA section 5(e)(1)(A)(ii)(I) where EPA determined that activities associated with the PMN substances may present unreasonable risk to human health or the environment. Those consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called "TSCA section 5(e) SNURs" on these PMN substances are promulgated pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent orders. The TSCA section 5(e) SNURs designate as a "significant new use" the absence of the protective measures required in the corresponding consent orders.

This rule also includes SNURs on 20 PMN substances that are not subject to consent orders under TSCA section 5(e). In these cases, for a variety of reasons, EPA did not find that the use scenario described in the PMN triggered the determinations set forth under TSCA section 5(e). However, EPA does believe that certain changes from the use scenario described in the PMN could result in increased exposures, thereby constituting a "significant new use." These so-called "TSCA non-section 5(e) SNURs" are promulgated pursuant to § 721.170. EPA has determined that every activity designated as a "significant new use" in all TSCA non-section 5(e) SNURs issued under § 721.170 satisfies the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified" for the PMN substance.

PMN Number P-11-549

Chemical name: 2-Butene, 1,1,1,4,4,4-hexafluoro-, (2Z)-.

CAS number: 692-49-9.

Basis for action: The PMN states that the generic (non-confidential) use of the substance

will be as a heat transfer fluid. Based on test data on the PMN substance as well as

structure activity relationship (SAR) analysis of analogous small fluorinated compounds,

EPA identified concerns for cardiac sensitization, developmental toxicity, neurotoxicity,

reproductive toxicity and oncogenicity from inhalation exposures to the PMN substance.

As described in the PMN, occupational exposures are expected to be minimal due to no

domestic manufacture and consumer exposure is not expected due to no use of the

substance in a consumer product. Therefore, EPA has not determined that the proposed

processing or use of the substance may present an unreasonable risk. EPA has

determined, however, that any domestic manufacture, any use other than as described in

the PMN, or any use of the substance in a consumer product may cause serious health

effects. Based on this information, the PMN substance meets the concern criteria at §

721.170 (b)(3)(i) and (b)(3)(ii).

Recommended testing: EPA has determined that inhalation monitoring data, collected

according to the EPA draft Inhalation Monitoring Data Collection Guidelines (located in

the docket under docket ID number EPA-HQ-OPPT-2015-0220) would help characterize

the human health effects of the PMN substance.

*CFR citation:* 40 CFR 721.10830.

PMN Number P-13-690

Chemical name: Aluminum phosphate (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the substance will be used as a flame retardant for industrial plastics. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung effects, blood toxicity, hypersensitivity, developmental neurotoxicity, and immunotoxicity from inhalation exposures to the PMN substance. Further, based on ecological SAR analysis of test data on analogous aluminum salts, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 87 parts per billion (ppb) of the PMN substance in surface waters. As described in the PMN, occupational exposures are expected to be minimal due to use of respiratory protection, and releases of the substance are not expected to result in surface water concentrations that exceed 87 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the PMN substance without the use of National Institute of Occupational Safety and Health (NIOSH)certified respirator with an assigned protection factor (APF) of at least 10, where inhalation exposures are expected, or any use of the substance resulting in surface water concentrations exceeding 87 ppb may cause serious human health effects and significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at 40 CFR 721.170 (b)(3)(ii) and (b)(4)(ii). Recommended testing: EPA has determined that the results of a 90-day inhalation

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or Organisation for Economic Cooperation and Development (OECD) Test Guideline 413); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test

Guideline 850.1300); and an algal toxicity test (Office of Chemical Safety and Pollution Prevention (OCSPP) Test Guideline 850.4500) would help characterize the human health and environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substance and mixtures (OECD Test Guideline 23) be consulted to facilitate solubility of the PMN substance in the test media.

CFR citation: 40 CFR 721.10831.

### PMN Number P-13-872

Chemical name: Alkyl triazine (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the substance will be used in the removal of hydrogen sulfide. Based on test data on the PMN substance, as well as ecological SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 130 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 130 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 130 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(4)(i) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test

(OPPTS Test Guideline 850.1300) would help characterize the environmental effects of

the PMN substance.

CFR citation: 40 CFR 721.10832.

PMN Number P-13-930

*Chemical name*: Substituted bis 2,6-xylenol (generic).

CAS number: Claimed confidential.

Effective date of TSCA section 5(e) consent order: December 10, 2014.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-

confidential) use of the substance will be as a reactant in polymerization reactions. Based

on SAR analysis of test data on structurally similar substances, EPA identified concerns

for liver, kidney and developmental toxicity; blood effects, sensitization, and endocrine

disruption. Further, based on test data on the PMN substance, EPA predicts toxicity to

aquatic organisms at concentrations that exceed 6 ppb of the PMN substance in surface

waters. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I),

based on a finding that the substance may present an unreasonable risk of injury to the

environment and human health, and there may be significant (or substantial) human

exposure to the substance. To protect against these exposures and risks, the consent order

requires:

1. Use of personal protective equipment involving impervious gloves and

protective clothing (where there is a potential for dermal exposure) and a NIOSH-

certified respirator with an APF of at least 50 (where there is a potential for inhalation

exposure).

2. Establishment and use of a hazard communication program, including human

health, environmental hazard precautionary statements on each label and the MSDS.

3. Manufacturing, processing, or use of the PMN substance only as an

intermediate.

4. Submission of certain toxicity testing prior to exceeding the confidential

production volume limits of the PMN substance specified in the consent order.

5. No predictable or purposeful release of the PMN substance from

manufacturing, processing or use into the waters of the United States that result in surface

water concentrations exceeding 6 ppb.

The SNUR designates as a "significant new use" the absence of these protective

measures.

Recommended testing: EPA has determined that the results of certain toxicity testing,

identified in the TSCA 5(e) consent order would help characterize possible effects of the

substance. The submitter has agreed not to exceed the first confidential volume limit

without performing an aromatase (human recombinant) test (OCSPP Test Guideline

890.1200) and a steroidogenesis (human cell line-H295R) test (OCSPP Test Guideline

890.1550 or OECD Test Guideline 456). Further, the Order prohibits the Company from

exceeding the second confidential production volume limit unless the Company submits

the Tier 2 testing described in the Testing section of this Order in accordance with the

conditions specified in the Testing section.

CFR citation: 40 CFR 721.10833.

PMN Number P-14-20

Chemical name: Heteropolycyclic diacrylate (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a coating resin. Based on test data on the PMN, EPA identified concerns for dermal and ocular irritation, and systemic toxicity from the dermal, ocular, and oral routes. Further, based on ecological SAR analysis of test data on analogous acrylates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 120 ppb of the PMN substance in surface waters. As described in the PMN, occupational exposures are expected to be minimal due to the use of impervious gloves, goggles, and a NIOSH-certified particulate respirator with an APF of at least 10. Further, releases of the substance are not expected to result in surface water concentrations that exceed 120 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without the use of impervious gloves and goggles, when there is a potential dermal exposure; any use of the substance without a NIOSH-certified particulate respirator with an APF of at least 10, where there is a potential for inhalation exposures; or any use of the substance resulting in surface water concentrations exceeding 120 ppb may cause serious health effects and significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at  $\S 721.170(b)(3)(i)$  and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a combined repeated dose toxicity with the reproduction/developmental toxicity screening test (OPPTS Test Guideline 870.3650); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an

algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10834.

#### PMN Number P-14-66

Chemical name: 1,6-Hexanediamine, N1-(6-aminohexyl)-, polymer with 2-(chloromethyl)oxirane, N-(dithiocarboxy) derivs., sodium salts.

CAS number: 1459738-70-5.

Basis for action: The PMN states that the substance will be used as a water clarifier intermediate. Based on ecological SAR analysis of test data on analogous dithiocarbamates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a mysid acute toxicity test (OCSPP Test Guideline 850.1035); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test

Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10835.

**PMN Number P-14-209** 

Chemical name: Dimethylaminoalkyl alkene amide (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an adjuvant for non-Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)-regulated agricultural use products, an additive for pesticide formulations, and an additive for fertilizer formulations. Based on test data on the PMN substance, as well as ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts chronic toxicity to aquatic organisms may occur at concentrations that exceed 4 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20day criterion is derived from partial life cycle tests (daphnid chronic and fish early-life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the PMN substance to surface water exceed releases from the use described in the PMN. For the uses described in the PMN, environmental releases did not exceed the concentration of concern for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance other than as described in the PMN may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10836.

### **PMN Number P-14-452**

Chemical name: Substituted naphthalene polymer glycidyl ether (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) uses of the substance will be as a matrix resin for composite materials and a binder resin for electronic materials. Based on ecological SAR analysis of test data on analogous polyepoxides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS

Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10837.

### **PMN Number P-14-473**

Chemical name: Alkylpolycarboxylic acid, derivative, tris(fluorinatedalkoxy)alkyl ester salt (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be for coatings and printing applications. Based on ecological SAR analysis of test data on analogous anionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 6 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 6 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 6 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a water solubility study (OECD Test Guideline 105); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10838.

PMN Number P-14-476

Chemical name: Tricyclo[3.3.1.13,7]decan-1-amine, N,N-dimethyl-.

CAS number: 3717-40-6.

Basis for action: The PMN states that the generic (non-confidential) use of the substance

will be as an isolated intermediate. Based on ecological SAR analysis of test data on

analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at

concentrations that exceed 8 ppb of the PMN substance in surface waters. As described in

the PMN, releases of the substance are not expected to result in surface water

concentrations that exceed 8 ppb. Therefore, EPA has not determined that the proposed

manufacturing, processing, or use of the substance may present an unreasonable risk.

EPA has determined that any use of the substance resulting in surface water

concentrations exceeding 8 ppb may cause significant adverse environmental effects.

Based on this information, the PMN substance meets the concern criteria at §

721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage

toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS

Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500)

would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10839.

**PMN Number P-14-510** 

Chemical name: Sulfosuccinic acid ester, alkylamine derivs., sodium salt (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an industrial leather softener. Based on test data on the PMN substance as well as SAR analysis of test data on analogous anionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 94 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 94 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 94 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.

*CFR citation:* 40 CFR 721.10840.

criteria at § 721.170(b)(4)(i) and (b)(4)(ii).

### **PMN Number P-14-603**

Chemical name: Bismuth nitrate oxide  $(Bi_3(NO_3)O_4)$ .

*CAS number*: 1417164-49-8.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a proprietary degradation inhibitor additive in polymer-based insulation sheets. Based on test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung effects from inhalation exposures to the PMN substance. For the use

described in the PMN, significant inhalation exposures are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as listed in the PMN, or without respiratory protection, may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity study with a 60-day holding period (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10841.

### **PMN Number P-14-605**

Chemical name: Substituted cyclosiloxane (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the use of the substance will be as a refractive index modifier component for light-emitting diode (LED) chips. Based on the physical/chemical properties of the PMN substance (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999) and test data on structurally similar substances, the PMN substance is a potentially persistent, bioaccumulative, and toxic (PBT) chemical. EPA estimates that the PMN substance will persist in the environment more than 2 months and estimates a bioaccumulation factor of greater than or equal to 1,000. As described in the PMN notice, the PMN substance will not be released to water. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk.

EPA has determined, however, that any use of the substance other than as described in the PMN or resulting in releases to water may cause serious health effects and significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii), (b)(4)(ii), and (b)(4)(iii).

Recommended testing: EPA has determined that the results of a partition coefficient (n-octanol/water) test, estimation by liquid chromatography (OPPTS Test Guideline 830.7570 or OECD Test Guideline 117); a ready biodegradability test (OPPTS Test Guideline 835.3110 or OECD Test Guideline 301); a fish bioconcentration factor (BCF) test (OPPTS Test Guideline 850.1730 or (OECD Test Guideline 305); and a water solubility test (OECD Test Guideline 111) would help characterize the health and environmental effects of the PMN substance. Depending on the results of these tests, additional testing as identified in the PBT category may be recommended.

CFR citation: 40 CFR 721.10842.

## **PMN Numbers P-14-666 and P-14-668**

Chemical names: Substituted amide aromatic carboxylic acid, metal salt (generic).

CAS numbers: Claimed confidential.

Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be as morphology modifiers for plastics. Based on ecological SAR analysis of test data on analogous amides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 67 ppb of the PMN substance (P-14-666) and 39 ppb of the PMN substance (P-14-668) in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early-life stage tests) that typically range from 21 to 28 days in duration. EPA predicts

toxicity to aquatic organisms may occur if releases of the substances to surface water, from uses other than as described in the PMNs, exceed releases from the uses described in the PMNs. For the use described in the PMNs, environmental releases did not exceed 67 ppb (P-14-666) and 39 ppb (P-14-668) for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances other than as listed in the PMNs may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a ready biodegradability test (OPPTS Test Guideline 835.3110); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) on each PMN substance would help characterize their environmental effects.

CFR citation: 40 CFR 721.10843.

### **PMN Number P-14-763**

*Chemical name*: Graphene nanoplatelets having a predominant thickness of 1-10 layers with lateral dimension predominantly less than 2 microns.

CAS number: Not Available

Effective date of TSCA section 5(e) consent order: December 30, 2014.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be in printed electronics, solar energy, separations, and functional composites. Based on SAR analysis of test data on respirable, poorly

soluble particulates and analogous carbon nanomaterials, EPA identified concerns for pulmonary toxicity, oncogenicity, immunotoxicity, fibrosis, and lung toxicity from lung overload. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that these substance may present an unreasonable risk of injury to the environment and human health, and there may be significant (or substantial) human exposure to the substance. To protect against these exposures and risks, the consent order requires:

- 1. Use of personal protective equipment involving impervious gloves and protective clothing (where there is a potential for dermal exposure) and a NIOSH-certified respirator (where there is a potential for inhalation exposure).
- 2. Establishment and use of a hazard communication program, including human health, environmental hazard precautionary statements on each label and the MSDS.
- 3. Manufacturing, processing, or use of the PMN substance only as described in the consent order.
- 4. No use of the PMN substance using an application method that generates a vapor, mist, or aerosol.
- 5. Submission of certain toxicity testing prior to exceeding the confidential production volume limits of the PMN substances specified in the consent order.
- 6. No predictable or purposeful release of the PMN substances from manufacturing, processing or use into the waters of the United States.

  The SNUR designates as a "significant new use" the absence of these protective measures.

Recommended testing: EPA has determined that the results of certain particle size distribution and material characterization testing would be needed for the PMN substance. The company has agreed to submit the full chemical characterization testing described in the testing section of the consent order within the timeframes identified in the order. Further, depending on the results of the characterization testing, additional toxicity testing may be required at a confidential aggregate manufacture volume, as detailed in the consent order.

CFR citation: 40 CFR 721.10844.

### **PMN Number P-14-781**

Chemical name: Methanaminium, N-[4-[[4-(dimethylamino)phenyl]phenylmethylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-, ethanedioate, ethanedioate (2:2:1).

CAS number: 2437-29-8.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a component of industrial inks and dyes. Based on test data on analogous malachite green chloride, pararosaniline, gentian violet, crystal violet, oxalic acid, and other analogous substances, EPA identified concerns for mutagenicity, carcinogenicity, eye irritation, as well as kidney, acute, and developmental toxicities for occupational inhalation exposures and general population exposures from drinking water exposures. In addition, based on ecological SAR analysis of test data on analogous cationic dyes, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, occupational exposures during processing and use activities are expected to be minimal. Further, releases of the PMN substance are not expected to result in surface water concentrations that exceed 1

ppb. Therefore, EPA has not determined that the proposed processing or use of the substance may present an unreasonable risk. EPA has determined, however, that any domestic manufacture of the substance, or any release of the substance resulting in surface water concentrations exceeding 1 ppb may cause serious health effects and significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a combined repeated dose toxicity with the reproduction/developmental toxicity screening test (OECD Test Guideline 422); a bacterial reverse mutation test (OECD Test Guideline 471); an in vitro mammalian chromosome aberration test (OECD Test Guideline 473); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health an environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10845.

### PMN Number P-14-811

Chemical name: Sulfurized hydrocarbon (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the use of the substance will be as a lubricant additive. Based on ecological SAR analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the low molecular weight components of PMN substance in surface waters. As described in the PMN, where 80 percent of the molecular weight species is greater than

1,000 daltons, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb of the low molecular weight components. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance where less than 80 percent of the molecular weight species is greater than 1,000 daltons, may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii). Recommended testing: EPA has determined that the results of an inherent biodegradability Zahn-Wellens test (OECD Test Guideline 302); an aerobic and anaerobic transformation in soil test (OECD Test Guideline 307); a fish BCF test: aqueous and dietary exposure (OECD Test Guideline 305); a bioaccumulation in sediment-dwelling benthic oligochaetes test (OECD Test Guideline 315); a sedimentwater chironomid toxicity test using spiked sediment (OECD Test Guideline 218); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance. CFR citation: 40 CFR 721.10846.

### **PMN Number P-14-821**

*Chemical name*: Oxiranemethanaminium, *N,N,N*-trimethyl-, bromide.

CAS number: 13895-77-7.

*Basis for action*: The PMN states that the substance will be used as an intermediate for polymer production. Based on test data on analogous epoxides, EPA identified concerns for skin and lung sensitization, mutagenicity, oncogenicity, developmental toxicity, male

reproductive, liver, and kidney toxicity from dermal and inhalation exposures. Further, based on ecological SAR analysis of test data on analogous quaternary ammonium compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 28 ppb of the PMN substance in surface waters. As described in the PMN, particulate exposures are not expected and releases of the substance are not expected to result in surface water concentrations that exceed 28 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any manufacture, processing, or use of the substance in the form of a powder or any use of the substance resulting in surface water concentrations exceeding 28 ppb may cause serious health effects and significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii) and (b)(4)(ii). Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465); a bacterial reverse mutation test (OPPTS Test Guideline 870.5100); a ready biodegradability test (OECD Test Guideline 301D) closed bottle method; a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10847.

#### **PMN Number P-14-875**

Chemical name: Aryloxyalkyl amine (generic).

CAS number: Claimed confidential.

Based on test data on the PMN substance and SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 44 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 44 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use resulting in surface water concentrations exceeding 44 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a ready biodegradability test (OECD Test Guideline 301) and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10848.

### **PMN Numbers P-15-115 and P-15-116**

*Chemical names*: (P-15-115) Phenol-biphenyl-formaldehyde polycondensate (generic); (P-15-116) Polymer of phenol, biphenyl and resorcinol (generic).

CAS numbers: Claimed confidential.

Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be in electric molding. Based on test data on the PMN substances as well as SAR analysis of test data on analogous phenols, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 5 ppb of the PMN substances in surface waters. As described in the PMNs, releases of the substances are not expected to

result in surface water concentrations that exceed 5 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use resulting in surface water concentrations exceeding 5 ppb may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a water solubility test (OECD Test Guideline 105); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substances. Testing may be conducted on either P-15-115 or P-15-116 and results should include a GPC analysis of molecular weight distribution.

CFR citations: 40 CFR 721.10849 (P-15-115) and 40 CFR 721.10850 (P-15-116)

# V. Rationale and Objectives of the Rule

### A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these SNURs, EPA concluded that for 2 of the 22 chemical substances, regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The SNUR provisions for these chemical substances

are consistent with the provisions of the TSCA section 5(e) consent orders. These SNURs are promulgated pursuant to § 721.160 (see Unit VI.).

In the other 20 cases, where the uses are not regulated under a TSCA section 5(e) consent order, EPA determined that one or more of the criteria of concern established at § 721.170 were met, as discussed in Unit IV.

### B. Objectives

EPA is issuing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this rule:

- EPA will receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- EPA will be able to regulate prospective manufacturers or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.
- EPA will ensure that all manufacturers and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory).

Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at

http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html.

### VI. Direct Final Procedures

EPA is issuing these SNURs as a direct final rule, as described in § 721.160(c)(3) and § 721.170(d)(4). In accordance with § 721.160(c)(3)(ii) and § 721.170(d)(4)(i)(B), the effective date of this rule is [insert date 60 days after date of publication in the Federal Register] without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before [insert date 30 days after date of publication in the Federal Register].

If EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs before [insert date 30 days after date of publication in the **Federal Register**], EPA will withdraw the relevant sections of this direct final rule before its effective date. EPA will then issue a proposed SNUR for the chemical substance(s) on which adverse or critical comments were received, providing a 30-day period for public comment.

This rule establishes SNURs for a number of chemical substances. Any person who submits adverse or critical comments, or notice of intent to submit adverse or critical comments, must identify the chemical substance and the new use to which it applies.

EPA will not withdraw a SNUR for a chemical substance not identified in the comment.

### VII. Applicability of the Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture

review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA section 5(e) consent orders have been issued for 2 of the 22 chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which would be designated as significant new uses. The identities of 16 of the 22 chemical substances subject to this rule have been claimed as confidential and EPA has received no post-PMN *bona fide* submissions (per §§ 720.25 and 721.11). Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

Therefore, EPA designates [insert date of publication in the Federal Register] as the cutoff date for determining whether the new use is ongoing. Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions, expires. If such a person met the conditions of advance compliance under § 721.45(h), the person would be considered exempt from the

requirements of the SNUR. Consult the **Federal Register** document of April 24, 1990 for a more detailed discussion of the cutoff date for ongoing uses.

#### VIII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. The two exceptions are:

- 1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
- 2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. lists those tests. Unit IV. also lists recommended testing for non-5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the OCSPP test guidelines referenced in this document electronically, please go to <a href="http://www.epa.gov/ocspp">http://www.epa.gov/ocspp</a> and select "Test Methods and Guidelines." The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at <a href="http://www.oecdbookshop.org">http://www.oecdbookshop.org</a> or SourceOECD at <a href="http://www.sourceoecd.org">http://www.sourceoecd.org</a>.

In the TSCA section 5(e) consent orders for several of the chemical substances regulated under this rule, EPA has established production volume limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Under recent TSCA section 5(e) consent orders, each PMN submitter is required to submit each study before reaching the specified production limit. Listings of the tests specified in the TSCA section 5(e) consent orders are included in Unit IV. The SNURs contain the same production volume limits as the TSCA section 5(e) consent orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture, or processing.

The recommended tests specified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
  - Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

### IX. Procedural Determinations

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI, at 40 CFR 721.1725(b)(1).

Under these procedures a manufacturer or processor may request EPA to determine whether a proposed use would be a significant new use under the rule. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical substance and must identify the specific use for which it intends to manufacture or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in § 721.1725(b)(1) with that under § 721.11 into a single step.

If EPA determines that the use identified in the *bona fide* submission would not be a significant new use, i.e., the use does not meet the criteria specified in the rule for a significant new use, that person can manufacture or process the chemical substance so long as the significant new use trigger is not met. In the case of a production volume trigger, this means that the aggregate annual production volume does not exceed that identified in the *bona fide* submission to EPA. Because of confidentiality concerns, EPA does not typically disclose the actual production volume that constitutes the use trigger. Thus, if the person later intends to exceed that volume, a new *bona fide* submission would be necessary to determine whether that higher volume would be a significant new use.

#### X. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and § 721.25. E-PMN software is available electronically at <a href="http://www.epa.gov/opptintr/newchems">http://www.epa.gov/opptintr/newchems</a>.

#### XI. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2015-0220.

#### XII. Statutory and Executive Order Reviews

#### A. Executive Order 12866

This action establishes SNURs for several new chemical substances that were the subject of PMNs, or TSCA section 5(e) consent orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993).

# B. Paperwork Reduction Act (PRA)

According to PRA (44 U.S.C. 3501 et seq.), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this action. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

# C. Regulatory Flexibility Act (RFA)

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

- 1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- 2. The SNUR submitted by any small entity would not cost significantly more than \$8,300.

A copy of that certification is available in the docket for this action.

This action is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit XI. and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- Submission of the SNUN would not cost any small entity significantly more than \$8,300.

Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

# D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

#### E. Executive Order 13132

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999).

#### F. Executive Order 13175

This action does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This action does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this action.

#### G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

#### H. Executive Order 13211

This action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

#### I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

#### J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

# **XIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

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# **List of Subjects**

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: May 28, 2015

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR parts 9 and 721 are amended as follows:

# PART 9--[AMENDED]

1. The authority citation for part 9 continues to read as follows:

**Authority:** 7 U.S.C. 135 et seq., 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 et seq., 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 et seq., 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. In § 9.1, add the following sections in numerical order under the undesignated center heading "Significant New Uses of Chemical Substances" to read as follows:

# § 9.1 OMB approvals under the Paperwork Reduction Act.

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40 CFR citation				OMB control No.						
*	*	*	*	*	*	*				
Significant New Uses of Chemical Substances										
*	*	*	*	*	*	*				
721.1	0830			2070-0012						
721.1	0831			2070-0012						
721.1	0832			2070-0012						
721.1	0833			2070-0012						
721.1	0834			2070-0012						
721.1	0835			2070-0012						

721.10836			2070-0012		
721.10837			2070-0012		
721.10838			2070-0012		
721.10839			2070-0012		
721.10840			2070-0012		
721.10841			2070-0012		
721.10842			2070-0012		
721.10843			2070-0012		
721.10844			2070-0012		
721.10845			2070-0012		
721.10846			2070-0012		
721.10847			2070-0012		
721.10848			2070-0012		
721.10849			2070-0012		
721.10850			2070-0012		
* *	*	*	*	*	*

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# PART 721--[AMENDED]

3. The authority citation for part 721 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

4. Add § 721.10830 to subpart E to read as follows:

# § 721.18030 2-Butene, 1,1,1,4,4,4-hexafluoro-, (2Z)-.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as 2-butene, 1,1,1,4,4,4-hexafluoro-, (2Z)- (PMN P-11-549; CAS No. 692-49-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(f), (j), and (o).
  - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
  - 5. Add § 721.10831 to subpart E to read as follows:

# § 721.18031 Aluminum phosphate (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as aluminum phosphate (PMN P-13-690) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance that has been completely reacted (cured) or entrained into a polymer matrix.
  - (2) The significant new uses are:

- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(4) and (a)(6)(1). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. A National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an Assigned Protection Factor (APF) of at least 10 meet the requirements of § 721.63(a)(4).
- (ii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=87).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (e), and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
  - 6. Add § 721.10832 to subpart E to read as follows:

#### § 721.10832 Alkyl triazine (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as alkyl triazine (PMN P-13-872) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:

- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=130).
  - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
  - 7. Add § 721.10833 to subpart E to read as follows:

# § 721.10833 Substituted bis 2,6-xylenol (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as substituted bis 2,6-xylenol (PMN P-13-930) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance that have been incorporated into an article or has been incorporated into a polymer matrix.
  - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), (b)(concentration set at 1.0 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g.,

workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 50 meet the requirements of § 721.63(a)(4):

- (A) NIOSH-certified power air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.
- (B) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.
- (C) NIOSH-certified negative pressure (demand) supplied-air respirator with a full facepiece.
- (ii) *Hazard communication*. Requirements as specified in § 721.72(a), (b), (c), (d),
  (e), (f)(concentration set at 1.0 percent), (g)(1)(The PMN substance may cause sensitization, eye irritation, internal organ effects, and developmental effects), (g)(2),
  (g)(3), (g)(4)(i), and (g)(5).
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(g) and (q).
- (iv) *Release to water*. (A) Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) N=6. However the requirements of § 721.91(a)(4) do not apply. Instead, if control technologies are in place to treat the waste stream containing the PMN substance, the amount of the PMN substance reasonably likely to be removed from the waste stream by such treatment may be subtracted in calculating the number of kilograms releases. No more than 40 percent removal efficiency may be attributed to such treatment.

- (B) In lieu of calculating the quotient, monitoring or alternative calculations may be used to predict the surface water concentrations expected to result from the intended release of the substance, if the monitoring procedures or calculations have been approved for such purposes by EPA.
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.
  - 8. Add § 721.10834 to subpart E to read as follows:

# § 721.10834 Heteropolycyclic diacrylate (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as heteropolycyclic diacrylate (PMN P-14-20) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(2)(iii), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), (b) (concentration set at 1.0 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement

of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

- (A) NIOSH-certified power air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.
- (B) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.
- (ii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=120).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (e), and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
  - 9. Add § 721.10835 to subpart E to read as follows:
- $\S$  721.10835 1,6-Hexanediamine, N1-(6-aminohexyl)-, polymer with 2-(chloromethyl)oxirane, N-(dithiocarboxy) derivs., sodium salts.
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as 1,6-Hexanediamine, N1-(6-aminohexyl)-, polymer with

2-(chloromethyl)oxirane, *N*-(dithiocarboxy) derivs., sodium salts (PMN P-14-66; CAS No. 1459738-70-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=1).
  - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
  - 10. Add § 721.10836 to subpart E to read as follows:

# § 721.10836 Dimethylaminoalkyl alkene amide (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as dimethylaminoalkyl alkene amide (PMN P-14-209) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(j).
  - (ii) [Reserved]

- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.
  - 11. Add § 721.10837 to subpart E to read as follows:

# § 721.10837 Substituted naphthalene polymer glycidyl ether (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as substituted naphthalene polymer glycidyl ether (PMN P-14-452) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=1).
  - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers and processors of this substance.

- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
  - 12. Add § 721.10838 to subpart E to read as follows:

# § 721.10838 Alkylpolycarboxylic acid, derivative, tris(fluorinatedalkoxy)alkyl ester salt (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as alkylpolycarboxylic acid, derivative, tris(fluorinatedalkoxy)alkyl ester salt (PMN P-14-473) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=6).
  - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
  - 13. Add § 721.10839 to subpart E to read as follows:

#### § 721.10839 Tricyclo[3.3.1.13,7]decan-1-amine, *N*,*N*-dimethyl-.

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as tricyclo[3.3.1.13,7]decan-1-amine, N,N-dimethyl- (PMN

P-14-476; CAS No. 3717-40-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=8).
  - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
  - 14. Add § 721.10840 to subpart E to read as follows:

# § 721.10840 Sulfosuccinic acid ester, alkylamine derivs., sodium salt (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as sulfosuccinic acid ester, alkylamine derivs., sodium salt (PMN P-14-510) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=94).
  - (ii) [Reserved]

- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
  - 15. Add § 721.10841 to subpart E to read as follows:

#### § 721.10841 Bismuth nitrate oxide ( $Bi_3(NO_3)O_4$ ).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as bismuth nitrate oxide (Bi<sub>3</sub>(NO<sub>3</sub>)O<sub>4</sub>) (PMN P-14-603; CAS No. 1417164-49-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63 (a)(4), (a)(6)(i), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 10 meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying elastomeric half-mask respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.

- (ii) Industrial commercial, and consumer activities. Requirements as specified in § 721.80(j).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (d), and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.
  - 16. Add § 721.10842 to subpart E to read as follows:

# § 721.10842 Substituted cyclosiloxane (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as substituted cyclosiloxane (PMN P-14-605) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Industrial commercial, and consumer activities*. A significant new use is any use other than as a refractive index modifier component for light-emitting diode (LED) chips.
- (ii) *Release to water*. Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
  - 17. Add § 721.10843 to subpart E to read as follows:

#### § 721.10843 Substituted amide aromatic carboxylic acid, metal salt (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substances identified generically as substituted amide aromatic carboxylic acid, metal salt (PMNs P-14-666 and P-14-668) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Industrial commercial, and consumer activities*. Requirements as specified in § 721.80(j).
  - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers and processors of these substances.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.
  - 18. Add § 721.10844 to subpart E to read as follows:
- § 721.10844 Graphene nanoplatelets having a predominant thickness of 1-10 layers with lateral dimension predominantly less than 2 microns.
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as graphene nanoplatelets having a predominant thickness of 1-10 layers with lateral dimension predominantly less than 2 microns (PMN P-14-763) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance that have been embedded or incorporated into a polymer matrix that itself has been reacted (cured); embedded in a permanent solid polymer form that is not intended to undergo further processing, except mechanical processing; or imported into an article as defined at 40 CFR 720.3(c).
  - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), (b) (concentration set at 1.0 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators meet the requirements of § 721.63(a)(4):

- (A) NIOSH-certified power air-purifying, tight-fitting full-face respirator equipped with an N-100, P-100, or R-100 cartridge.
- (B) NIOSH-certified power air-purifying particulate respirator with an assigned protection factor (APF) of at least 50.
- (ii) Industrial, commercial, and consumer activities. Requirements as specified in \$721.80(k), (q), and (y)(1).
- (iii) *Release to water*. Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (e), (i), and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of \$721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.
  - 19. Add § 721.10845 to subpart E to read as follows:
- \$ 721.10845 Methanaminium, N-[4-[[4-(dimethylamino)phenyl]phenylmethylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-, ethanedioate, ethanedioate (2:2:1).
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as methanaminium, *N*-[4-[[4-(dimethylamino)phenyl]phenylmethylene]-2,5-cyclohexadien-1-ylidene]-*N*-methyl-, ethanedioate, ethanedioate (2:2:1) (PMN P-14-781; CAS No. 2437-29-8) is subject to

reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
- (i) *Industrial commercial, and consumer activities*. Requirements as specified in § 721.80(f).
- (ii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=1).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
  - 20. Add § 721.10846 to subpart E to read as follows:

# § 721.10846 Sulfurized hydrocarbon (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as sulfurized hydrocarbon (PMN P-14-811) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Industrial commercial, and consumer activities*. Requirements as specified in § 721.80. A significant new use is any use where less than 80 percent of the low molecular weight species are greater than 1,000 daltons.

- (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.
  - 21. Add § 721.10847 to subpart E to read as follows:

#### § 721.10847 Oxiranemethanaminium, N,N,N-trimethyl-, bromide.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as oxiranemethanaminium, *N*,*N*,*N*-trimethyl-, bromide (PMN P-14-821; CAS No. 13895-77-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Industrial commercial, and consumer activities*. Requirements as specified in § 721.80(v)(1), (w)(1), and (x)(1).
- (ii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=28).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
  - 22. Add § 721.10848 to subpart E to read as follows:

#### § 721.10848 Aryloxyalkyl amine (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as aryloxyalkyl amine (PMN P-14-875) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=44).
  - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
  - 23. Add § 721.10849 to subpart E to read as follows:

#### § 721.10849 Phenol-biphenyl-formaldehyde polycondensate (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as phenol-biphenyl-formaldehyde polycondensate (PMN P-15-115) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=5).
  - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
  - 24. Add § 721.10850 to subpart E to read as follows:

# § 721.10850 Polymer of phenol, biphenyl and resorcinol (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as polymer of phenol, biphenyl and resorcinol (PMN P-15-116) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=5).

- (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

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